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Methodological, Practical, and Ethical Challenges to Inner-City Health Research

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ABSTRACT *Inner-city health research can be challenging because it deals with vulnerable populations and sometimes puts investigators in difficult situations. Some challenges are methodological, including selecting the optimal research design, implementing effective methods of recruitment and retention, and determining the best approach to data analysis. Other issues are practical, including addressing potential biases in social research; dealing with conflicting research agendas among investigators, community agencies, and funding agencies; and disseminating research findings effectively. Another set of issues relates to the ethical conduct of research, including ensuring privacy, maintaining confidentiality, and obtaining consent that is informed, not coerced, and not influenced by undue inducements. Throughout the research endeavor, the inner-city health researcher must carefully balance the roles of investigator, advocate, activist, and caregiver.*

INTRODUCTION

Consider four illustrative examples, each based on real-life situations that inner-city health researchers have experienced.

- *Example 1: The Intoxicated Potential Participant.* You are conducting a study of an intervention targeted to homeless persons who have alcoholism. On interviewing a potential participant, you suspect that he is intoxicated. You arrange follow-up appointments, but at the next two meetings, he is again intoxicated. Do you proceed with obtaining informed consent?
- *Example 2: Research and Politics.* The director of a community agency calls you regarding a welfare policy change. The director asks you to collaborate on a study that will demonstrate the negative health effects of the new policy. You are concerned that it will be difficult to demonstrate adverse outcomes because the policy change is recent, and the outcomes are difficult to measure, yet you are sympathetic to the director's point of view. What do you say to her?
- *Example 3: Paying Crack Cocaine Users.* In conducting a longitudinal study of crack cocaine users, you give participants $20 for each follow-up visit they attend. A caseworker informs you that your participants are high the day after each visit and asks you to stop paying participants. He says that

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you are contributing adversely to the crack epidemic in your city. Do you stop paying subjects?

- *Example 4: The Investigator's Responsibility.* You are the principal investigator of a community-based intervention study to increase the rate of cervical cancer screening among women in the inner city. The control group receives information pamphlets about the importance of screening, but no further intervention. As the study gets under way, you realize that the majority of women in the control group have not received any screening for many years and are still not seeking it based on the information pamphlets provided. Your colleague asserts that it is your responsibility to help these women and asks if you would consider changing the study protocol to allow for additional interventions directed at women in the control group.

These examples illustrate some of the distinctive methodological, practical, and ethical challenges facing inner-city health researchers. Many issues relate to the vulnerability to adverse health outcomes of the populations being studied as inner-city residents have higher-than-average rates of poverty, social instability, recent immigration, mental illness, substance use, and intoxication.[1] Other issues stem from a consideration of the role of the researcher, whose level of engagement may exceed that of investigators in other domains.

In this article, we review issues inner-city researchers may face related to the design of a research project, the recruitment and retention of participants, data collection and analysis, and dissemination of research findings. We also explore some personal dilemmas investigators may confront.

DESIGNING A RESEARCH PROJECT

As with all scientific inquiry, inner-city health research must be demonstrably interesting, relevant, and feasible.[2] Yet, "mission-based" research that defines itself in terms of a socially disadvantaged region may raise questions about the purpose of the endeavor: can the scientific question be disentangled from the motivations, often rooted in social justice considerations, that inspired the research? The best defense against such biases is to acknowledge that they can—and do—exist, to be transparent in the way the research is conducted, and to be vigilantly self-critical in reporting both positive and negative results.

A related challenge arises when the agendas of the research partners conflict. Community, scientific, and policy agendas may frequently diverge, even when deciding whether a potential research question is interesting. Similarly, funding opportunities, and not community needs assessments, often drive research agendas.[3] Dialogue is important for overcoming mistrust or suspicion that may exist between partners, but such discussions are often lengthy.[4] We believe that inner-city health scientists need to be flexible in their approach to research, that they should be in constant dialogue with community members, and that their obligations in collaboration include generation of knowledge for community-based partners, even when such activities do not necessarily lead to peer-reviewed publications. Community partners should also appreciate that such time demands on researchers will be difficult until community-based activities are recognized and rewarded in academic environments.

RECRUITMENT

The reason most often cited why recruitment for studies conducted in the inner city may be particularly challenging is mistrust. Potential participants' suspicions may originate from individuals' experiences with the health care system, experiences with other research studies, a general aversion to authority, experiences with systematic discrimination, or past abuses by health researchers.[5] Successful recruitment strategies start from an awareness and appreciation of the potential tensions of the researcher-participant relationship and may include collaborating with community-based organizations, using peer recruiters, investing time to address sensitive questions, and using methods throughout the study that are flexible, adaptive, and sensitive to participants' needs.[6]

Informed consent is a concern in studies that recruit individuals with mental illness or substance abuse problems and in studies of populations with a high prevalence of these conditions, such as homeless people.[7] Other conditions that may make obtaining consent difficult include low literacy and lack of fluency in the languages of the research study. Researchers in the inner city need to establish explicit procedures to ensure that study participants have the capacity to give consent, and that they comprehend the specifics of the consent process.[8,9] Examples include translating consent forms into languages other than English, rewriting consent forms in low-literacy versions, and using nonwritten methods such as videotape to communicate important messages. Researchers and research ethics boards should also recognize that capacity to consent can vary in an individual patient at different times. Furthermore, the requisite level of capacity necessary to consent should reflect the unique set of risks associated with each research study.

Mental health research provides several important lessons to consider when obtaining consent to participate in research studies.[10] First, a diagnosis of severe and persistent mental illnesses—even an illness as limiting as schizophrenia—is less important for determining capacity than the presence of specific symptoms and impairments, including apathy, avolition, inappropriate affect, and disorganized behavior. Second, specific instruments to evaluate decisional capacity to consent to participate in research exist, but these instruments frequently require modification for specific studies and careful interpretation.[11] Third, such instruments may be most useful in identifying areas of the consent process that require specific remediation.

A central tenet of consent is that it should be voluntary. The US Office of Human Research Protection's definition of voluntary, derived from the *Belmont Report*, is consent that is "free of coercion, duress, or undue inducement."[12] Issues of coercion and duress (compulsion through the use or threat of force) may be of particular concern for individuals whose autonomy and other freedoms are limited due to extremes of impoverishment or restrictions imposed by the judicial system. To the extent that inner-city health researchers recruit from these groups, investigators need to ensure that individuals are not consenting for the wrong reasons—for example, because they fear that shelter workers or the police will punish them for their decision.

Similarly, research participants should not consent because they are unable to resist the associated rewards offered for participating. Although such "undue inducements" could include leniency from social service and justice officials or nonmonetary material rewards such as vouchers, questions most commonly arise when researchers offer potential recruits money in exchange for participating. Even when

compensating subjects is deemed acceptable, setting the appropriate amount may be difficult.[13] Suggestions include setting the monetary amount at a level that is not excessive and that is calculated based on time or contribution[14] or setting the compensation rate at the level of low-wage, unskilled labor.[15] Yet, even low rates may sometimes be an undue inducement for inner-city residents as the potential for undue inducement is greatest when "a person is economically destitute and truly has no other options for acquiring comparable amounts of money."[14(p.42)] Other considerations in setting an appropriate compensation also need to be considered. Too high a rate may truly act as an undue inducement; too low a rate may introduce a selection bias into a study by dissuading participation among those individuals, such as the working poor, who cannot afford to forego their regular source of income.[16] Practically, research ethics boards will need to determine the "appropriate" compensation rates according to local circumstances, the particulars of a project, and their own sense of fairness.[15]

Privacy and confidentiality are paramount concerns when study participants suffer from conditions such as human immunodeficiency virus (HIV) infection that are potentially stigmatizing or who are engaged in illegal activities, such as the possession or sale of illicit drugs. Researchers collecting sensitive information should consider obtaining a Certificate of Confidentiality, which is issued by the National Institutes of Health (NIH), to protect research information from forced disclosure in civil, criminal, and other proceedings.

While researchers almost always inform subjects about procedures designed to safeguard confidentiality, they less frequently discuss the limits of confidentiality with research participants.[9] For example, researchers may be bound to break confidentiality and take action if they discover that a research participant is actively homicidal or suicidal or engaged in child abuse or neglect. Research ethics boards should ensure that researchers have policies and procedures for managing these and other critical events; these policies and procedures should be developed in advance of undertaking any study in which these situations could conceivably occur.

RETENTION OF STUDY SUBJECTS

Several circumstances raise major challenges to conducting longitudinal studies that seek to measure changes in health behaviors and health status over time. For example, inner-city residents are often highly transient, and a significant number lack a home telephone.[17] Important techniques for successful retention of inner-city residents in research studies include obtaining multiple alternate contacts outside the participant's household, making studies flexible enough to schedule follow-up interviews on evenings and weekends, offering financial incentives for follow-up, and using computerized databases and telephone search methods.[17] Longitudinal contact with homeless people can be facilitated through community agencies that maintain close ties with these individuals.[18]

DATA COLLECTION AND ANALYSIS

Quantitative, particularly observational, inner-city health research often considers individuals as members of communities, neighborhoods, cities, or some combination thereof. Researchers should clearly state the assumptions behind the classification of such aggregate groups: Exactly how large is a neighborhood? Which characteristics are the residents assumed to have in common? How will one set neighborhood boundaries? Researchers who perform aggregate-level analyses also need to guard

against the ecologic fallacy, in which they inappropriately make inferences at one analytical level (for example, individuals) from studies focused on a different unit of analysis (for example, neighborhoods). Multilevel methods, in which hierarchical systems are used to classify the potential units of analysis, are often an appropriate and appealing method for quantitative statistical analysis of inner-city projects.[19] Researchers planning interventional studies face a related set of concerns, in which the level of intervention (for example, community) may not be the same as the level at which outcomes are measured (for example, individuals).

Researchers working with confidential or potentially sensitive data need to balance these issues against their own instincts for free scientific inquiry. Although advances in data management make collection, storage, and linkage of data much easier than in the past, researchers should practice restraint in the mining of such data sources. Real or perceived unfettered access may quickly engender mistrust and disillusionment. We believe that appropriate consultation with community representatives, research ethics boards, and if appropriate, the original data custodians is a prudent and reasonable path for researchers to follow when planning data analyses beyond the scope of the original data collection or research project.

Qualitative researchers face their own set of challenges, particularly at the time of data collection. Although qualitative interviewers always need to be aware of how their own biases and beliefs may guide the interview process, such considerations may be particularly important in settings in which individuals have been harmed, such as victims of violence. One method of demonstrating rigor in qualitative research is to appeal to external standards; an alternative conceptualization of rigor starts from an assessment of inquiry as intrinsically value laden.[20] Such a paradigm, which evaluates each choice in the process of inquiry against the implicit and explicit values behind the decisions, may be beneficial for all inner-city health researchers.

DISSEMINATION OF FINDINGS

Research conducted in the inner city faces special challenges in the dissemination of research findings.[4] Community members may express frustration and displeasure at researchers who harvest data, but depart without sharing their results. Front-line workers and advocates may favor immediate release of research results through the media in the hopes of rapidly affecting public policy, a strategy that conflicts with the relatively slow timeline of the academic cycle and may jeopardize publication in a peer-reviewed journal. Communicating unpopular findings may also be a source of conflict. Researchers should discuss and negotiate these issues with community representatives at the outset of the research effort. When communicating with the media, both researchers and community members should use concise language that is not prone to misinterpretation, avoids negative stereotyping, and states policy implications clearly.

ROLE OF THE RESEARCHER

Inner-city researchers can find themselves facing personal dilemmas relating to their potentially conflicting roles of scientists, policy advocates, and political activists. Does political engagement jeopardize scientific integrity? Are investigators who study socially unjust situations obligated to explore methods that enact remedial changes? Among researchers, the limit of appropriate activism may be writing a

letter to the editor, risking arrest in acts of civil disobedience, or seeking political office or appointment. Because this choice reflects individual values, we neither expect nor desire consensus regarding the appropriate upper limits of political engagement. However, we do feel that a lower limit exists; in our view, it is problematic for investigators to research the inner city with no sense of political engagement. At a minimum, investigators should acknowledge that framing a research question pertaining to the health of the disadvantaged is frequently a political act itself.

Another dilemma that researchers may face relates to their obligations to their research subjects. Investigators, particularly those who are also health care providers, may find themselves in situations in which they have identified individuals with remediable conditions. Investigators need to think carefully about what level of involvement they will have in helping their research participants navigate complicated systems—whether in health or social services—to find the care they need and how this involvement may influence their research project. From a health services perspective, investigators and funding agencies need to think carefully about their obligations for facilitating or providing ongoing care that is being delivered within the context of a research project, but that ceases when funding runs out.

THE EXAMPLES

We return now to the examples presented above, discuss some possible approaches, and indicate our preferred options. While we appreciate that our decisions may be controversial, we present them in the spirit of collaborative learning, recognizing that we may be wrong and eager to hear the points of view of others.

- *Example 1: The Intoxicated Potential Participant*. Should one obtain consent from an intoxicated patient? Many would answer that this is unacceptable at any time. However, intoxication may not always impair judgment beyond that necessary to consent. We would apply an external reference standard of competency to assess not whether individuals are intoxicated, but whether their judgment is too impaired to consent.
- *Example 2: Research and Politics*. How should investigators respond to requests for research that serves a political agenda? Some would decline participation to maintain scientific objectivity and integrity. Others would consider participating, but insist on rigorous scientific standards. Still others would offer to speak publicly as an expert in the area, drawing on previous research to speak to the policy options being proposed. We favor a combination of the last two approaches.
- *Example 3: Paying Crack Cocaine Users*. Should researchers stop paying crack cocaine users who are buying drugs with their reimbursement? Many would agree with discontinuing compensation, arguing that the public health and political implications override other concerns. An alternative approach is to continue payment, but to decrease the amount. Our preferred approach would be to continue with the current research protocol for three reasons. First, the amount has previously been judged by a research ethics board to be a reasonable compensation. Second, changing the study would jeopardize both retention and reputation. Third, arbitrary restrictions on payment amounts based on what individuals might do with the amount—even illegal activities—are paternalistic and ethically problematic.

- *Example 4: The Investigator's Responsibility.* Does an investigator have a responsibility to intervene with control research subjects if the investigator discovers that they are receiving a substandard level of care? A negative response stems from an argument that it is important to maintain scientific integrity for the duration of the study and that opportunities for intervention will come after the study is completed. An affirmative response stems from an argument that ethical imperatives and community obligations compel the investigator to change the protocol in midstream and deal with the resultant "dirty data" in subsequent analyses. We favor continuing with the current protocol because the harm from waiting until this study is over to improve cervical cancer screening rates is minimal. However, a more important lesson is the importance of foresight by investigators and reviewers when designing such a study to avoid such problematic situations.

CONCLUSION

The same issues that make improving the health of inner-city disadvantaged populations compelling also make research in the field challenging. Successfully navigating these challenges requires strict scientific and ethical standards, a clear perception of one's values and how these could potentially bias research, and sensitivity to political issues at the individual, community, and policy levels. Reaching a consensus on many issues may not be possible. What is imperative, however, is that each investigator explicitly considers issues relevant to his or her research, engages in dialogue with the inner-city communities in which they work, and develops cogent reasons for the choices that they ultimately make.

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